This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.



May 5, 1999

Via Facsimile

Mr. Robert C. McNally
Special Review Branch Chief
Special Review and Reregistration Division
Office of Pesticide Programs
United States Environmental Protection Agency
Mail Code 7508W
401 M Street, S.W.
Washington, D.C. 20460

Re: DDVP Draft Preliminary Risk Assessment

Dear Bob:

Following the recent submittal (May 4, 1999) of additional information pertinent to the DDVP Risk Assessment, Amvac feels it appropriate to make the following comments on the process used by EPA.

Amvac once again expresses its concern with the timetable EPA has felt itself obliged to impose. Amvac is of the view that the DDVP draft Preliminary Risk Assessment (PRA) ignores a large body of highly relevant studies. A summary or cursory review of these studies will be insufficient to conduct a thorough and fair evaluation of the weight-of-the-evidence in the DDVP risk assessment. Amvac has attempted, and will continue to attempt, to assist EPA in conducting the type of review that is necessary for a sound risk assessment. It is unfortunate that the Agency has felt it appropriate to impose a timetable on Amvac for providing this information, when it is clear to Amvac that it is not possible to provide the type of information and analyses that are critical for the thorough review that EPA, I am sure, wishes to produce within this timetable. Given EPA's plan to release the DDVP PRA to the public in the next several weeks, Amvac strongly urges the Agency to revise this timetable and allow the thorough review to be completed.

Your letter states: "EPA will review the rationale submitted by Amvac by April 30 as part of its effort to address Amvac's concerns and open the docket," but that "subsequent additional information . . . will be considered by EPA after the docket opens as part of the substantive comment period for the PRA." Amvac has emphasized that the information it submitted

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on April 30 was preliminary and that more thorough analyses were needed. Indeed the interim document was submitted in an attempt to assist the Agency in its thorough review of the DDVP database, given the imposed timetable. The documents that Amvac submitted yesterday supplement the April 30, 1999, submission, but they are not -- because of the time constraints that EPA has imposed on Amvac -- the thorough analyses I am sure both of us would like to see to ensure a scientifically sound risk assessment. Amvac is aware that EPA has serious resource constraints that make it difficult for it to review the studies and other materials that it previously has received from Amvac. Additional resources will also be required to incorporate the studies and other materials in a revised draft PRA and to allow Amvac an opportunity to comment on that revised PRA, but Amvac wishes to emphasize that it will do all it can to assist EPA to expedite the full review.

As I am sure you appreciate, Amvac is particularly concerned about the damage that the premature release of an incomplete risk assessment can do to both the credibility of the Agency and Amvac's commercial interests. A relatively minor change in the timetable will avoid both of these. Unlike many other organophosphates, DDVP has its major sales in the consumer market, which is very susceptible to adverse comment, however preliminary that comment may be. This is particularly true given that EPA's public release of the PRA with its current conclusions will effectively function as a final agency regulatory decision. The public release of the PRA will send a clear message to the world that DDVP pesticide products pose too great a risk to warrant continued registration. Viewers of the EPA web site will reasonably conclude that EPA has taken final action and that cancellation of the pest strips and other DDVP products is imminent. Adverse publicity in the newspapers and on television, among other media, is inevitable. Consumers will stop purchasing and using Amvac DDVP products, and this damage cannot be undone even if EPA ultimately revises the PRA.

In summary, Amvac urges EPA not to release the DDVP PRA on the timetable that it has announced. EPA should instead consider in a meaningful fashion the large body of studies that Amvac has submitted, as well as Amvac's analyses, and revise the PRA accordingly. Amvac then should be provided an adequate opportunity to comment on the revised PRA, and EPA should have an adequate opportunity to consider and incorporate those comments, before it releases the PRA.



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Amvac looks forward to your response.

Sincerely

Ian S. Chart

cc: Marcia E. Mulkey, Esquire

Mr. Jack E. Housenger Mr. Dennis Utterback

Ms. Pam Noyes